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17 March 2023

**Via CM/ECF**

The Honorable Evelyn Padin, U.S.D.J.  
United States District Court for the District of New Jersey  
Frank R. Lautenberg Post Office Building and U.S. Courthouse  
One Federal Square  
Newark, NJ 07102

**Re: Metacel Pharmaceuticals, LLC v. Rubicon Research Private Limited**  
**U.S.D.C.(D.NJ)**  
**C.A. No. 2:21-cv-19463-EP-JRA**

Dear Judge Padin:

We represent Rubicon Research Private Limited ("Rubicon") in the above matter. We write in response to the letter submitted on the evening of March 16, 2023 from Metacel's counsel asking the court to dismiss Rubicon's motion for summary judgment of non-infringement. Respectfully, Metacel's request is misleading inasmuch as fails to acknowledge the clear and distinct section III of Rubicon's brief in support of summary judgment titled "Relevant Undisputed Facts." Moreover, both (a) the procedural posture of this case, including the prolonged period Metacel has had possession of Rubicon's motion and neglect to previously raise this particular issue despite previously objecting to the motion, and (b) the timing of the letter, essentially on the eve Metacel's response is due, strongly indicate Metacel's motion is nothing more than a last-ditch effort to avoid summary judgment.

The facts of this case are not complicated. As detailed in Rubicon's motion, Rubicon's product (a) lacks buffers, including specifically citric acid; (b) is not tested for the baclofen-citric acid impurity, a necessary step of the claimed invention, because it lacks citric acid and, thus, lacks the impurity; and (c) is not refrigerated, also an essential step of the claimed inventions (ECF 88 at 2.) These are the material facts in favor of summary judgment, and, Metacel's assertions to the contrary notwithstanding, they are set out clearly and distinctly in section III of Rubicon's brief beginning at page 15 (ECF 89 at 15-17.) These facts are preceded in Rubicon's brief by undisputed facts pertaining to the patent-in-suit and its prosecution history (ECF 89 at 7-17.) Therefore, Metacel's complaint is totally unfounded. At most, Metacel can complain that the factual statements

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were not numbered, but, given that Metacel chose to wait until only a few days before its response is due, to raise this issue, and given the simplicity of facts before the Court, Rubicon respectfully submits Metacel's letter request to strike the motion should be denied and Metacel should be required to respond by the current deadline of March 20, 2023.

Rubicon notes Metacel has already requested Rubicon's motion for summary judgment be dismissed on technical grounds and the request was denied. Rubicon's motion was filed on February 10, 2023. Metacel thereafter attempted to block Rubicon's motion and delay these proceeding by arguing that the motion was untimely under this Court's Scheduling Order. This effort was denied on February 16, 2023, and Metacel was ordered to respond to Rubicon's motion on March 20, 2023 (*See* Order at ECF 93.)

Metacel did not raise the technical issue it writes about currently in its previous effort to block and delay Rubicon's motion, and there is no legitimate explanation for Metacel to get a further opportunity to disrupt these proceedings with a second basis. Rubicon reminds the Court that Metacel has had Rubicon's motion papers since July 27, 2022 (changed only to add the Court's Markman Order), so it cannot credibly claim that it was unaware of the issue it now raises on the eve of it finally being compelled to respond to Rubicon's motion.

Metacel's complaint that it is "impossible" to develop its opposition papers due to the technical issue it writes about currently is an incredible assertion given the argument raised by Rubicon in its briefing, as Rubicon's position on non-infringement has been crystal clear since the inception of this case and Metacel has extended this frivolous litigation to where it now is causing anti-competitive injury to Rubicon<sup>1</sup>. As was made clear in Rubicon's original filing nearly 8 months ago (ECF 39-41.) Metacel cannot meet its burden of proving infringement because of an absence of three separate limitations required in both of the claims of the patent in litigation, the '502 patent.

Metacel has never had a valid basis for bringing this action as has been clear to Metacel since production of Rubicon's ANDA more than 1 year ago. The specific bases explaining why Metacel cannot meet its burden with respect to each of these required claim limitations has been laid bare and unchanged since July 27, 2022, and Metacel has resisted any effort to properly set forth its case and now faces a court ordered deadline of this coming Monday to do so. Rubicon respectfully submits that the impossibility repeatedly complained of in Metacel's letter is occasioned by the frivolous nature of its claims here, which Metacel has long been aware with great specificity on Rubicon's part.

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<sup>1</sup> Rubicon's ANDA No. 217324 received tentative approval effective March 13, 2023.

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Nothing substantive about Rubicon's motion has changed for the last 8 months. The absence of evidence, the basis for Rubicon's motion since Metacel has the burden of proving its case, was explicitly described and has been unchanged for the last 8 months. The only change in this matter during this time occurred this week, with Rubicon receiving Tentative Approval for its ANDA product on March 13, 2023– a fact which Metacel was notified of on March 15. This means that the only reason Rubicon is unable to launch its ANDA product is the continued existence of this sham litigation, which is frivolous and is now causing active and provable anti-competitive injury to Rubicon.

Finally, Rubicon respectfully submits that it is not out of compliance with Local Rule 56.1, except that it did not file a separate document with numbered paragraphs (ECF 89 at 7-17.) Rubicon's brief in support of its motion for summary judgment has a separate section of relevant undisputed facts beginning on page 7 and continuing through page 17. The facts (essentially the patent claims and specification (13 paragraphs), the prosecution history (5 paragraphs) and Rubicon's ANDA (6 paragraphs)) set forth therein are described as relevant undisputed facts and cite to affidavits and other documents submitted in connection with the motion, all as required by rule.

Against this backdrop, Metacel's delay in bringing this "issue" to the Court, its long-standing knowledge of Rubicon's non-infringement position, its previous attempts and most recent failure to prevent this day from coming, its use of these proceedings to inflict anti-competitive injury on Rubicon, and the detailed and uncontroversial facts properly and plainly described in Rubicon's motion papers, Metacel's claim that it would be unfair and prejudicial to Metacel to require it to finally respond substantively to the challenge to the fundamental legitimacy of this lawsuit is absurd. Now that Rubicon's ANDA has been approved but for the existence of this lawsuit, the prejudice suffered by Rubicon for every day it continues vastly outweighs Metacel's procedural complaint.

For these reasons, Rubicon respectfully requests that the Court deny Metacel's letter request and that the March 20, 2023 date for response to Rubicon's motion for summary judgment remain intact.

Respectfully yours,

A handwritten signature in black ink, appearing to read "R. Touhey Myer", with a stylized, flowing script.

R TOUHEY MYER

RTM/rec

cc: All Counsel of Record (*via CM/ECF*)